REMARKS

I. Status of the Claims

Claims 39-58 are pending.[1] No claims have been amended by this response.

II. Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 39-58 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Office Action at page 2. Applicant respectfully disagrees and traverses this rejection for at least the following reasons.

The Examiner asserts that it is not clear which subject matter Applicant regards as the invention. Office Action at page 2. The Examiner further asserts that the preamble of claim 39 "calls for an apparatus," but "the body of the claim recites the steps of making a stent from a substrate tube comprising three layers." *Id.* Finally, the Examiner asserts that Applicant has claimed both an intermediate product as a substrate tube having two cladding layers as well as a final product as stent being made from the intermediate product." *Id.*

A rejection under 35 U.S.C. § 112, second paragraph, is appropriate if the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement. *See Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993); M.P.E.P. § 2173.02 (emphasis added). The claim must not be

[1] The Office Action incorrectly identifies claims 39-**59** as pending and rejected. *See* Office Action Summary and pages 2 and 3 of the Office Action. In reality, claims 39-**58** are currently pending in the present application.

rejected under 35 U.S.C. § 112, second paragraph, if the language used by Applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used. M.P.E.P. § 2173.02.

Applicant respectfully submits that the claim limitations clearly define the scope of the claim to one of ordinary skill in the art. Further, Applicant is at a loss as to the Examiner's assertion that the body of the claims recites the steps of making a stent from a substrate tube comprising three layers. Claim 39 recites:

> A laminate stent for implantation within a body lumen, comprising:
> a substrate tube formed from a superelastic alloy and having an exterior surface;
> a first cladding layer formed from a metallic material and bonded to the exterior surface of the substrate tube;
> a second metallic radiopaque cladding layer bonded to the first layer thereby forming a laminate tube; and
> a stent pattern formed in the laminate tube such that the resultant laminate stent includes a plurality of radially expandable cylindrical elements disposed generally coaxially and interconnected by elements disposed between adjacent cylindrical elements, the cylindrical elements and the interconnecting elements being entirely formed of the substrate tube, the first cladding layer, and the second metallic radiopaque cladding layer.

Applicant notes that claim 39 does not recite a single method step. Each element recited in the claim is a structural element of the laminate stent. Applicant further notes that the use of the phrase "formed from" is <u>not</u> a method step. Rather, the phrase "formed from" is used to identify the composition of the element to which it refers.

With respect to the Examiner's assertion that Applicant has claimed both an intermediate product and a final product, Applicant respectfully submits that one of

ordinary skill in the art would clearly understand the claim to be directed to a laminate stent comprising a substrate tube, a first cladding layer, a second metallic radiopaque layer, and a stent pattern formed on the laminate tube which is comprised of the substrate tube, the first cladding layer, and the second metallic radiopaque layer. The phrase "laminate tube" is not used to define an intermediate product. Rather, it is used to define the structural relationship between the substrate tube, the first cladding layer, and the second metallic radiopaque layer.

For at least the foregoing reasons, Applicant respectfully submits that the claims clearly point out and distinctly claim the subject matter the Applicant regards as the invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

III. Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 39-58 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,922,020 to Klein et al. ("Klein") in view of U.S. Patent No. 5,919,126 to Armini ("Armini") for the reasons disclosed on pages 3-4 of the Office Action. Applicant respectfully disagrees and traverses this rejection for at least the following reasons.

The Examiner asserts that Klein discloses a "stent being made from either stainless steel but suggest it can be made from superelastic, shape memory alloy (col. 5, lines 40-57) . . . and the stent being plated with radiopaque materials (col. 10, lines 30-45)." *See* Office Action at page 3.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. M.P.E.P. § 2143.01. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Additionally, a prior art reference must be considered in its entirety. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Applicant respectfully submits that the Examiner has inappropriately applied the references in this rejection because a careful reading of the references in their entirety shows that Klein and Armini do not teach all of the elements recited in the claims.

Klein does not teach a stent made from a superelastic material and plated with radiopaque materials. There is only a single disclosure of a tubular prosthesis made of a superelastic material in Klein. *See* Klein at col. 5, lines 39-47. In that passage, Klein discloses a fourth aspect of the invention which comprises a method of fluoroscopically viewing a target region within a body lumen. *Id.* In the method disclosed by Klein, the "prosthesis is positioned in the body lumen while observing the fluoroscopic image of the entire prosthesis." *Id.* Klein then discloses that "[t]ypically, such prosthesis will be malleable and composed of stainless steel, but the method may also apply to superelastic, shape memory alloy, and other self-deploying prosthesis." *Id.* (emphasis added).

Nowhere within the disclosure of Klein does Klein teach or suggest that the tubular prosthesis can be formed of a superelastic material plated with a radiopaque material. Klein merely discloses that a superelastic tubular prosthesis may be used in a method of fluoroscopically viewing a target region within a body lumen. *See* Klein at col. 5, lines 45-48. While Klein does teach that stainless steel can be plated with a radiopaque layer (see, e.g., col. 5, lines 23-37 and 45-46), Klein does not teach that the superelastic material can be plated with a radiopaque layer. Any assertion to the contrary is akin to hindsight reconstruction based on an inappropriate piecemeal analysis and combination of the various teachings of Klein.

Instant claim 40 recites that the superelastic alloy of the substrate tube is nickel-titanium. Klein teaches that "[s]tents composed of nickel titanium alloys and other radiopaque materials can be readily observed fluoroscopically if the cross-sections of their components are sufficiently large." Klein at col. 2, lines 19-22. Assuming the Examiner's assertion is accurate, it is not clear why one would have been motivated to add a radiopaque layer to a radiopaque material, absent the improper reliance on Applicant's disclosure. Rather, Klein does teach that it would be desirable to increase the fluoroscopic properties of **radiolucent** materials, such as stainless steel. Based on the teachings of Klein, one skilled in the art would not have been motivated to plate a nickel-titanium alloy with a radiopaque layer. Klein only suggests the use of radiopaque materials to adjust the radiopacity of radiolucent materials, such as stainless steel. *See* Klein at col. 10, lines 30-45 (teaching in relevant part that, "such plating is particularly

desirable with stainless steel and other material which **are not inherently radiopaque**") (emphasis added).

Armini fails to cure the deficiencies of Klein because Armini does not teach or suggest a laminate stent comprising, *inter alia*, a substrate tube formed of a superelastic alloy, a first cladding layer formed from a metallic material and bonded to the exterior surface of the substrate tube, and a second metallic radiopaque cladding layer bonded to the first layer, as recited in the present claims. Admittedly, the Examiner relies on Armini for its teaching of an adhesive layer used in metals or alloys.

For at least the foregoing reasons, Applicant submits that the combination of Klein and Armini does not teach all of the elements of the claimed invention. Therefore the Examiner has not established a *prima facie* case of obviousness. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

IV. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims 39-58.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

MICHELE C. BOSCH REG. NO. 40,524

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By: Michele C. Bosch
for Louis M. Troilo
Reg. No. 45,284